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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WILSON, MICHAEL C

ART UNIT PAPER NUMBER

1632

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/044,006

Applicant(s)

BAGUISI ET AL.

Examiner

Michael C. Wilson

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5 and 25, drawn to an avian gonad cell comprising a heterologous nucleic acid, classified in class 435, subclass 325.
- II. Claims 6-22, drawn to a method of introducing a nucleic acid sequence into the genome of an avian comprising contacting gonad cells isolated from a chick embryo with a nucleic acid molecule and transferring the cells to a fertilized recipient embryo, classified in class 800, subclass 21.
- III. Claim 23, drawn to a gonad cell having a disruption of an endogenous gene that inhibits the production of functional gene product, classified in class 435, subclass 325.
- IV. Claim 24, drawn to an avian egg having a xenogeneic PGC, classified in class 435, subclass 325.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are patentably distinct because the cells of Group I have a different scope than those required for Group II. In addition, the cells of group I do not have to be used to introduce a nucleic acid into the genome of an avian as in Group II. For example, the cells of Group I may be a PGC cell line expressing a growth factor.

Groups I and III are patentably distinct because the cells of Group I express heterologous proteins while the cells of Group III do not. The cells of Group III have a

Art Unit: 1632

disruption in an endogenous gene while the cells of Group I do not. The cells of Group I have a heterologous nucleic acid while the disruption of a gene in the cells of Group III may occur naturally.

Group I and IV are patentably distinct because the cells of Group I may be used to make an avian expressing a heterologous protein while the egg of Group IV may be used to make an avian of two different species. The egg of Group IV does not require a heterologous nucleic acid as in Group I. The cells of Group I do not have to be used in a xenogeneic species as in Group IV.

Groups II and III are patentably distinct because the method of Group II is used to make transgenic avians while the cells of Group III may be used to create a PGC cell line that does not produce a protein. The cells of Group III have a disruption in an endogenous gene while the cells used in the method of Group II do not. The cells used in the method of Group II have a nucleic acid while the disruption of a gene in the cells of Group III may occur naturally.

Group II and IV are patentably distinct because the cells used in the method of Group II may be used to make an avian expressing a heterologous protein while the egg of Group IV may be used to make an avian of two different species. The egg of Group IV does not require a nucleic acid as in Group II. The cells used in the method of Group II do not have to be used in a xenogeneic species as in Group IV.

Group III and IV are patentably distinct because the cells of Group III may be used to make an avian that does not produce a particular protein (knockout avian) while the egg of Group IV may be used to make an avian of two different species. The egg of

Art Unit: 1632

Group IV does not require a disruption in a gene as in the cells of Group III. The cells of Group III do not have to be used in a xenogeneic species as in Group IV.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.


Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson



**MICHAEL WILSON**  
**PRIMARY EXAMINER**